K132031

510(k) SAFETY AND EFFECTIVENESS SUMMARY

This summary of 510(k) safety and efficacy information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: k132031

Submission type: **510 (k)**

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Preparation date: 21 June 2013

Device Name: Afinion™ Lipid Panel and Afinion™ Lipid Panel Control

Product code	Classification	Regulation Section	Panel
CHH - Total Cholesterol*	Class I	21 CFR 862.1175	75-Chemistry
LBR – HDL Cholesterol*	Class I	21 CFR 862.1475	75-Chemistry
JGY – Triglycerides*	Class I	21 CFR 862.1705	75-Chemistry
JJX – Quality Control material*	Class I	21 CFR 862.1660	75-Chemistry

*Meets limitations of the exemption as per 21 CFR 862.9(c)(4).

Predicate Devices:
The predicate devices for Afinion™ Lipid Panel are the following legally marketed devices:

- Total Cholesterol
  Roche Diagnostics Corp.: COBAS INTEGRA CHOLESTEROL GEN.2; Submission K031824

- Triglycerides
  Roche Diagnostics Corp.: ROCHE COBAS INTEGRA REAGENT CASSETTES & ANCILLARY REAGENTS); Submission K972250

- HDL Cholesterol
  Siemens ADVIA 2400 Direct HDL Cholesterol; Submission K982341 (Original applicant: Randox laboratories, Ltd.)

The predicate device for Afinion™ Lipid Panel Control is the following legally marketed device:

- Clinica Corp.: CLINIQA Liquid QC Lipid Controls Levels 1 and 2; Submission K061182

Intended use/Indications for use

The Afinion™ Lipid Panel is an *in vitro* diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig) in serum. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion™ AS100 Analyzer. Chol, HDL cholesterol, Trig, and calculated LDL cholesterol, non-HDL cholesterol and Chol/HDL ratio) are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

Afinion™ Lipid Panel Control has been designed for use with the Afinion™ AS100 Analyzer and Afinion™ Lipid Panel. Afinion™ Lipid Panel Control is intended for use as assayed control material for total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig). The controls should be used to confirm that the Afinion™ AS100 Analyzer System is working properly and provides reliable results.

For use in clinical laboratories and point of care laboratory settings.

For prescription use only.

Principle of the assay

Afinion™ Lipid Panel is a fully automated assay for quantitative determination of Chol, HDL and Trig in serum. LDL, non- HDL and Chol/HDL are calculated by the Afinion™ AS100 Analyzer.

The Afinion™ Lipid Panel Test Cartridge contains all reagents necessary for determination of Chol, HDL and Trig in serum. The sampling device integrated in the test cartridge is filled with sample material. The test cartridge is then placed in the Afinion™ AS100 Analyzer. The analyzer inspects the sampling device, and the sample is then diluted.

Total Cholesterol (Chol)

Total Cholesterol is measured by an enzymatic colorimetric method. Esterified and free cholesterol are enzymatically converted into cholest-4-en-3-one and hydrogen peroxide. The hydrogen peroxide is used by hydrogen peroxidase to couple a phenol and 4-aminoantipyrin to a red quinoneimine dye. The color intensity is directly proportional to the concentration of free and esterified cholesterol in the sample.

Triglycerides (Trig)

Triglycerides are measured by an enzymatic colorimetric method. Triglycerides are enzymatically converted into glycerol by lipoprotein lipase. Glycerol is then further catalyzed in 2 steps to di-hydroxy-acetone-phosphate and hydrogen peroxide. The hydrogen peroxide then reacts with 4-aminophenazone and 4-chlorophenol under the action of peroxidase to form a red dyestuff. The

color intensity is directly proportional to the concentration of triglycerides.

HDL cholesterol
In a first reaction, anti-human apolipoprotein B (apoB) antibody (R1) binds to apoB present on all lipoproteins but HDL (i.e. non-HDL). The antibody protects non-HDL from being degraded by pegylated cholesterol metabolizing enzymes in the second reaction (R2). In the R2 reaction free and esterified cholesterol of HDL are converted into cholest-4-en-3-one and hydrogen peroxide. The hydrogen peroxide is used by peroxidase to couple 4-aminoantipyrin to F-DAOS and forms a blue color complex. The color intensity is directly proportional to the concentration of free and esterified HDL cholesterol.

LDL cholesterol
NCEP recommends calculating LDL by use of the Friedwald formula[2]:
LDL (mg/dL) = Chol – HDL – Trig/5
This equation is not valid for non-fasting specimen, or in patients with type III hyperlipoproteinemia. No LDL result is provided by the analyzer when triglyceride levels are above 400 mg/dL as the Friedwald formula is less accurate at these triglyceride concentrations.

non-HDL cholesterol
The sum of VLDL (very low density lipoprotein) + LDL is called non-HDL cholesterol. It is calculated routinely as total cholesterol minus HDL:
non-HDL = Chol – HDL

Chol/HDL ratio
Chol/HDL = Total Cholesterol/ HDL Cholesterol

Traceability of Afinion™ Lipid Panel
Chol and HDL are traceable to the National Reference System for Cholesterol (NRS/CHOL). Trig is traceable to a Centers for Disease Control and Prevention (CDC) reference method.

Afinion™ Lipid Panel is CRMLN certified for Total Cholesterol and HDL Cholesterol.

Afinion™ Lipid Panel Kit contents (per 15 tests unit)
- 15 Test Cartridges packaged separately in foil pouches
- 1 Package Insert

Materials required but not provided with the kit
- Afinion™ AS100 Analyzer
- Afinion™ Lipid Panel Control
- Standard blood collection equipment

Target value assignment and traceability of Afinion™ Lipid Panel Control
The Afinion™ Lipid Panel is used for target value assignment of the Afinion™ Lipid Panel Control C I and C II. The target values and the corresponding acceptable ranges printed in the labeling are derived from replicate analyses (n=18) and are specific for each lot of product. Testing is performed on one operating day using 3 or 6 analyzers. The tests are performed by the manufacturer using Afinion™ Lipid Panel test cartridges and a representative sampling of the control lot.
Chol and HDL are traceable to the National Reference System for Cholesterol (NRS/CHOL). Trig is traceable to a Centers for Disease Control and Prevention (CDC) reference method.

Estimated target values for Afinion™ Lipid Panel Control

Analyte	Target value range (mg/dL) Afinion™ Lipid Panel Control	
	Control CI	Control CII
Total cholesterol	165-210	230-280
HDL cholesterol	34-46	52-70
Triglycerides	130-170	250-305

Afinion™ Lipid Panel Control Stability
Real time stability studies were conducted to establish unopened and opened vial stability. Afinion™ Lipid Panel Control CI and CII were measured with the Afinion™ Lipid Panel assay. All results were compared to the initial baseline results.

The Afinion™ Lipid Panel Controls were continuously stored at 2-8 °C (36-46 °F). Testing was performed monthly for 12 months. The study is on-going.

Afinion™ Lipid Panel Control CI and CII were subjected to an opened vial (in-use) stressing study. The vials were stored at 2-8 °C (36-46 °F) in the periods between the test points. Testing was performed after 7, 14 and 30 days, and thereafter weekly until 8 weeks. In between these testing points the vials were opened and samples withdrawn twice a week.

The acceptance criteria for Total Cholesterol, HDL Cholesterol and Triglycerides were: Recovery to baseline within 100 ± 10 %.

The results from the stability studies support the following conclusions:

Shelf life: 12 months when stored refrigerated (2-8 °C, 36-46 °F)
Opened vials stability: 8 weeks when stored refrigerated (2–8°C, 36-46 °F).

Afinion™ Lipid Panel - Comparison of technological characteristics with predicate devices

Characteristic	**Roche Diagnostics Corp. Cholesterol**	**Afinion™ Lipid Panel Analyte: Total Cholesterol (Chol)**
Intended use	Enzymatic in vitro test for the direct quantitative determination of cholesterol in human serum and plasma on Roche automatic clinical chemistry analyzers	The Afinion™ Lipid Panel is an *in vitro* diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig) in serum. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion™ AS100 Analyzer. Chol, HDL cholesterol, Trig, and calculated LDL cholesterol, non-HDL cholesterol and Chol/HDL ratio) are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. For use in clinical laboratories and point of care laboratory settings.
Test principle	Enzymatic colorimetric test	Enzymatic colorimetric test.
Specimen type	Serum Plasma	Serum
Reporting range	3.86-800 mg/dL	100-500 mg/dL
Calibration	Calibrated periodically using calibrators supplied by vendor.	No calibration necessary by the user. Lot specific calibration via barcode on the cartridge. Calibration parameters are read by the analyzer from the barcode before each run.
Sample volume	Sample is automatically drawn from sample tube with a sample volume of at least 0.5 mL.	15 µL
Test time	10 minutes Batch testing	8 minutes Single tests
Testing environment	For use by health care professionals. Laboratory testing on automated clinical chemistry analyzers (Hitachi)	For use by health care professionals Point of care testing using automated analyzer (Afinion™ AS100 Analyzer)
Assay reagents	Bottle of Reagent 1.	Ready to use test cartridges
Control material	8 controls available.	Afinion Lipid Panel Control:

available from supplier of assay	Freeze-dried.	2 control levels. Ready to use.
Reagents and controls storage conditions	Refrigerated storage, 2-8 °C	Refrigerated storage, 2-8 °C

Characteristic	**Roche Diagnostics Corp. Triglycerides**	**Afinion™ Lipid Panel Analyte: Triglycerides (Trig)**
Intended use	Enzymatic in vitro test for the direct quantitative determination of triglyceride in human serum and plasma on Roche automatic clinical chemistry analyzers.	The Afinion™ Lipid Panel is an *in vitro* diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig) in serum. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion™ AS100 Analyzer. Chol, HDL cholesterol, Trig, and calculated LDL cholesterol, non-HDL cholesterol and Chol/HDL ratio) are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. For use in clinical laboratories and point of care laboratory settings.
Test principle	Enzymatic colorimetric test	Enzymatic colorimetric test.
Specimen type	Serum Plasma	Serum
Reporting range	8.85-885 mg/dL	45-650 mg/dL
Calibration	Calibrated periodically using calibrators supplied by vendor.	No calibration necessary by the user. Lot specific calibration via barcode on the test cartridge. Calibration parameters are read by the analyzer from the barcode before each run.
Sample volume	Sample is automatically drawn from sample tube with a sample volume of at least 0.5 mL.	15 µL
Test time	5 minutes Batch testing	8 minutes Single tests

Testing environment	For use by health care professionals. Laboratory testing on automated clinical chemistry analyzers (Hitachi)	For use by health care professionals Point of care testing using automated analyzer (Afinion™ AS100 Analyzer)
Assay reagents	Bottle of Reagent 1.	Ready to use test cartridges
Control material available from supplier of test	8 controls available. Freeze-dried.	Afinion Lipid Panel Control: 2 control levels. Ready to use.
Reagents and controls storage conditions	Refrigerated storage, 2-8 °C	Refrigerated storage, 2-8 °C

Characteristic	**Siemens ADVIA 2400** **HDL-Cholesterol**	**Afinion™ Lipid Panel** **Analyte: HDL Cholesterol**
Intended use	For in vitro diagnostic use in the quantitative determination of HDL cholesterol in human serum and plasma on the ADVIA Chemistry systems. Such measurements are used in the risk assessment of coronary artery disease	The Afinion™ Lipid Panel is an *in vitro* diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig) in serum. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion™ AS100 Analyzer. Chol, HDL cholesterol, Trig, and calculated LDL cholesterol, non-HDL cholesterol and Chol/HDL ratio) are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders. For use in clinical laboratories and point of care laboratory settings.
Test principle	Enzymatic colorimetric test. Direct determination of HDL-cholesterol. Cholesterol from non-HDL particles is eliminated in the first reaction step.	Enzymatic colorimetric test. Direct determination of HDL by initial antibody blocking of apolipoprotein B (apo-B) , which is present on all lipoproteins except HDL cholesterol.

	In second step cholesterol in HDL particles is released by detergent and measured by a Trinder reaction.	
Specimen type	Serum Plasma	Serum
Reporting range	5-115 mg/dL	15-100 mg/dL
Calibration	Calibrated periodically using calibrators supplied by vendor.	No calibration necessary by the user. Lot specific calibration via barcode on the cartridge. Calibration parameters are read by the analyzer from the barcode before each run.
Sample volume	Sample is automatically drawn from sample tube with a sample volume of at least 0.5 mL.	15 µL
Test time	10 minutes Batch testing	8 minutes Single tests
Testing environment	For use by health care professionals. Laboratory testing on automated clinical chemistry analyzers (ADVIA))	For use by health care professionals Point of care testing using automated analyzer (Afinion™ AS100 Analyzer)
Assay reagents	Bottles of Reagent 1 and Reagent 2	Ready to use test cartridges
Storage conditions	Refrigerated storage, 2-8 °C	Refrigerated storage, 2-8 °C
Control material	2 control levels recommended. Available from Bio-Rad Laboratories.	Afinion Lipid Panel Control: 2 control levels. Ready to use.

Afinion™ Lipid Panel Control - Comparison of technological characteristics with predicate device

Characteristic	Cliniqa Liquid QC Lipid Control	Afinion™ Lipid Panel Control
Similarities		
Intended Use	CLINIQA Liquid QC Lipid Control is intended for use as an assayed quality control material for Apolipoprotein A-1, Apolipoprotein B, Cholesterol (Total), High Density Lipoprotein, Low Density Lipoprotein and Triglycerides.	Afinion™ Lipid Panel Control is intended for use as assayed control material for total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig).
Matrix	Human serum	Human serum*
Analyte	Total Cholesterol HDL Cholesterol Triglycerides	Total Cholesterol HDL Cholesterol Triglycerides
Form	Liquid – ready to use	Liquid – ready to use
Levels	2	2
Storage conditions	2-8°C	2-8°C
Differences		
Analytes	Target values also available for ApoLipoprotein A1 and Apolipoprotein B and LDL Cholesterol.	No target values for ApoLipoprotein A1 and Apolipoprotein B as they are not measured by Afinion™ Lipid Panel. LDL cholesterol is calculated by Afinion™ AS100 Analyzer, and no target value for LDL is assigned.
Kit size	3 x 2 x 3 mL or L1: 6 x 3 mL and L2: 6 x 3 mL	2 x 1 x 1.0 mL
Target value assignment	Target values are method dependent, and assigned values are available for a large number of methods/systems.	Target values are assigned for Afinion™ Lipid Panel.

* Each serum/plasma donor unit used in the manufacture of the control products has been tested by FDA accepted methods and found non-reactive for the presence of HBsAg and antibody to HIV-1/2, HCV and HIV-1 Ag.

Linearity

The Afinion™ Lipid Panel assay has been demonstrated to be linear across the measuring ranges according to CLSI Guideline EP6-A. The study was performed measuring dilution series with serum samples. One low and one high sample were intermixed to produce 11 concentration levels for each analyte. Each level was measured in 4-6 replicates. The linear regression lines for comparison of measured concentration (y) and theoretical concentration (x) are:

Total cholesterol: $y=1.000x - 4.5$ mg/dL, $r^2=0.995$
Triglycerides: $y=1.009x - 2.9$ mg/dL, $r^2=0.999$
HDL Cholesterol: $y=0.991x - 2.4$ mg/dL, $r^2=0.994$

Linearity for Total Cholesterol, Triglycerides and HDL Cholesterol using serum samples has been demonstrated over the following ranges:

Total cholesterol:	77-511 mg/dL	(Reportable range 100-500 mg/dL)
Triglycerides:	36-691 mg/dL	(Reportable range 45-650 mg/dL)
HDL Cholesterol:	14-111 mg/dL	(Reportable range 15-100 mg/dL)

Limits of Quantitation

Limits of quantitation have been established according to CLSI Guideline EP-17A, which determines Limits of quantitation (LoQ) based on determination of limits of blank (LoB) and Limits of Detection (LoD). 5 samples with concentration near 0 mg/dL (LoB samples) were measured in totally 60 replicates using 3 analyzers and 2 Afinion™ Lipid Panel test cartridge lots. 5 low concentration samples (LoD samples) were tested according to the same test scheme. LoQ was estimated based on the established LoD.

The following limits of quantitation have been established for Afinion™ Lipid Panel in serum:

Analyte	Total Cholesterol	HDL Cholesterol	Triglycerides
LoQ (mg/dL)	13	1.3	5.9

Analytical specificity

Design verification studies have been performed to investigate whether any endogenous and exogenous substances interfere with the Afinion™ Lipid Panel assay. The studies have been performed in accordance with CLSI guideline EP7-A2.

Interference effect from 28 substances has been evaluated, among commonly used antibiotics, statins, analgesic agents, immune-suppressants and anticoagulants. The substances tested are those previously assessed within the predicate devices, substances found to interfere with lipid tests based on a literature search. In addition the most common drugs used for lipid-lowering therapy and diabetic management have been tested.

The substances listed below were tested for interference with the measurements of Chol, HDL and Trig. Samples covering two medical decision concentrations of each lipid analyte were measured. No significant interference (<10%) was observed up to the following concentrations:

- Acetaminophen 200 mg/L
- Acetylsalicylic acid 1000 mg/L
- Acetylcysteine 1590 mg/L
- Ampicillin 1000 mg/L
- Ascorbic acid 6 mg/dL
- Atorvastatin 600 µg/L
- Bilirubin (conjugated and unconjugated) 20 mg/dL
- Calcium dobesilate 0.7 mg/dL
- Cefoxitin 2500 mg/L
- CyclosporineA 5mg/L
- CyclosporineC 5mg/L
- Fluvastatin 2.97 mg/L
- Hemoglobin (hemolysis) 0.5 g/dL
- Heparin 3000 U/L
- Ibuprofen 500 mg/L
- Intralipid 10000 mg/L
- Levodopa 15 mg/L
- Lovastatin 216 µg/L
- Metformin 40 mg/L
- Methyldopa 1.4 mg/dL
- Metronidazole 200 mg/L
- Pravastatin 7.32 mg/L
- Rifampicin 64.3 mg/L
- Simvastatin 80.4 µg/L
- Theophylline 100 mg/L
- Tetracycline 50 mg/L

Limitations:

- Calcium dobesilate interferes with Afinion™ Lipid Panel at therapeutic levels and results in falsely low results for Chol, HDL and Trig.
- Methyldopa concentrations above 1.4 mg/dL interfere with Afinion™ Lipid Panel and may give falsely low Trig results. This is above toxic levels of Methyldopa and there is no interference at therapeutic levels.
- Acetylcysteine concentrations above 1590 mg/L may give falsely low Trig results. This is above the drug concentration at therapeutic level.
- Levodopa concentrations above 15 mg/L may give falsely low HDL and Trig results. This is above the drug concentration at therapeutic level.

Accuracy

A method comparison was performed between Afinion™ Lipid Panel and automated laboratory methods (CM) for Chol, Trig and HDL. The study was performed at four point-of-care sites. The study was performed according to CLSI guideline EP09-A2-IR, except that single replicates per sample was used for the Afinion™ Lipid Panel measurements and not duplicates as stated in the guideline. Regression analysis results for each analyte in serum are summarized in table 1. Bias at medical decision levels and elevated concentration levels are summarized in table 2. Bland-Altman plots are presented in figures 1-3.

Table 1 Method comparison results for serum.

Analyte	Number of samples	Intercept	Slope	Correlation coefficient (r)	Range
Chol	348	-4.5 mg/dL	1.04	0.99	105.5 - 466.0 mg/dL
Trig	246	-11.4 mg/dL	1.04	1.00	55.5-616.5 mg/dL
HDL	251	-2.1 mg/dL	1.04	0.98	23.2-92.7 mg/dL

Table 2 Calculated bias (in mg/dL and %) at different concentration levels for serum.

Analyte	Concentration level (mg/dL)	Bias (mg/dL)	Bias (%)
Trig	150	-5.0	-3.3
	200	-2.8	-1.4
	500	9.9	2.0
Chol	200	2.6	1.3
	240	4.0	1.7
	400	9.7	2.4
HDL	40	-0.6	-1.6
	60	0.1	0.1
	80	0.8	1.0

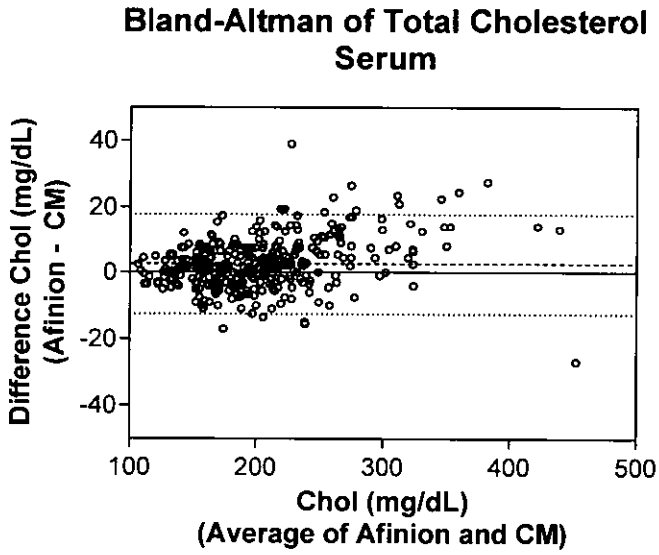

Figure 1 Bland-Altman plot of total cholesterol, serum. Difference in mg/dL.

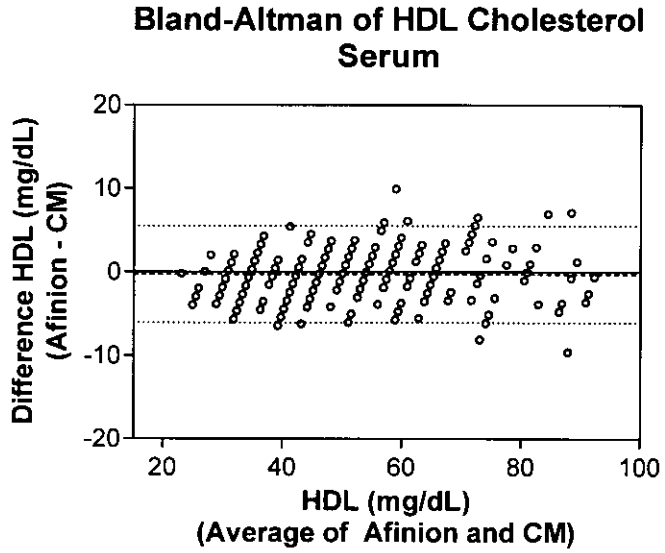

Figure 2 Bland-Altman plot of HDL cholesterol, serum. Difference in mg/dL.

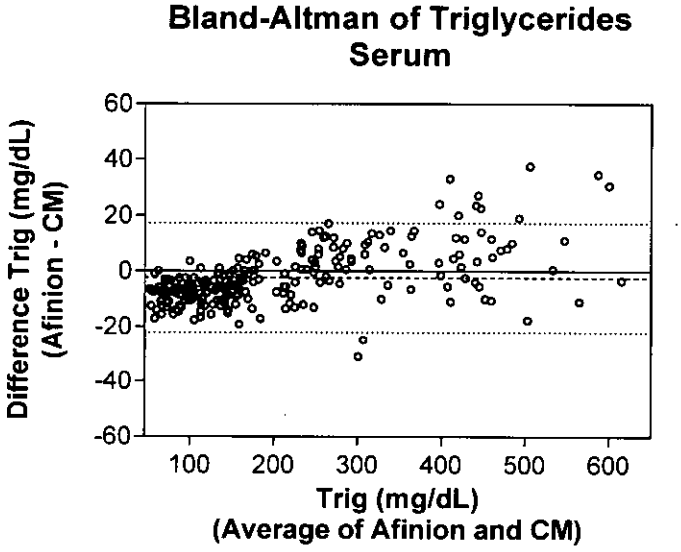

Figure 3 Bland-Altman plot of Triglycerides, serum. Difference in mg/dL.

Precision

Repeatability and within-device (total) precision were determined according to the CLSI Guideline EP5-A2. The precision study was performed at three point-of-care sites using one lot of Afinion™ Lipid Panel test cartridges and 2-3 analyzers per site.

Two controls and one serum sample were tested with 2 replicates per run and 2 runs per day for 20 days with a total of 80 replicates at each site. The results are summarized in tables 3-5.

Table 3: Cholesterol. Repeatability and Within-device precision (total), N=number of replicates, SD=Standard deviation, CV=Coefficient of Variation.

				Repeatability		Within-device	
	Site	N	Mean (mg/dL)	SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)
Control sample	1	80	185.8	3.2	1.7	4.3	2.3
	2	80	186.5	5.5	2.9	6.7	3.6
	3	80	186.3	5.8	3.1	5.6	3.0
Control sample	1	80	249.2	6.3	2.5	6.1	2.4
	2	80	252.4	6.2	2.4	9.8	3.9
	3	80	249.3	8.9	3.5	8.5	3.4
Serum sample	1	80	400.0	7.0	1.7	9.4	2.3
	2	80	401.4	10.2	2.5	12.4	3.1
	3	80	401.4	9.6	2.4	11.1	2.8

Table 4: HDL. Repeatability and Within-device precision (total), N=number of replicates, SD=Standard deviation, CV=Coefficient of Variation.

				Repeatability		Within-device	
	Site	N	Mean (mg/dL)	SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)
Control sample	1	80	39.8	1.1	2.7	1.3	3.2
	2	80	40.6	1.6	3.9	2.0	4.9
	3	80	40.1	1.1	2.8	1.2	3.1
Control sample	1	80	57.1	1.4	2.5	1.6	2.8
	2	80	59.4	2.1	3.5	2.6	4.4
	3	80	57.9	2.1	3.6	2.1	3.6
Serum sample	1	80	70.8	1.8	2.5	1.8	2.6
	2	80	72.8	1.6	2.2	3.0	4.1
	3	80	72.0	1.5	2.1	1.9	2.6

Table 5: Triglycerides. Repeatability and Within-device precision (total), N=number of replicates, SD=Standard deviation, CV=Coefficient of Variation.

				Repeatability		Within-device	
	Site	N	Mean (mg/dL)	SD (mg/dL)	CV (%)	SD (mg/dL)	CV (%)
Control sample	1	80	153.8	3.6	2.3	4.1	2.7
	2	80	154.5	3.9	2.5	5.4	3.5
	3	80	154.8	4.2	2.7	4.5	2.9
Control sample	1	80	276.2	7.1	2.6	7.1	2.6
	2	80	279.1	5.8	2.1	10.4	3.7
	3	80	276.0	12.2	4.4	13.4	4.9
Serum sample	1	80	343.5	6.3	1.8	7.4	2.2
	2	80	344.1	10.6	3.1	13.5	3.9
	3	80	343.3	9.3	2.7	12.3	3.6

Conclusion

Comparison of information characterizing the Afinion Total Cholesterol, Triglyceride and HDL Cholesterol assays and the Afinion Lipid Panel controls for use on the Afinion AS 100 Analyzer including results of the method comparison, precision, sensitivity, specificity, bias, and linearity studies, as well as the value assignment and stability studies for the Lipid Panel controls showed the results to be substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 21, 2014

AXIS-SHIELD POC AS
KARI SKINNEMOEN
P.O. BOX 6863
RODELOKKA
OSLO N-0504, NORWAY

Re: K132031
Trade/Device Name: Afinion™ Lipid Panel
Afinion™ Lipid Panel Control
Regulation Number: 21 CFR 862.1175
Regulation Name: Cholesterol (total) test system
Regulatory Class: I, Meets limitations of the exemption as per 21 CFR 862.9(c)(4).
Product Code: CHH, LBR, JGY, JJY
Dated: February 10, 2014
Received: February 12, 2014

Dear Ms. Skinnemoen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
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Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
k132031

Device Name
Afinion™ Lipid Panel and Afinion™ Lipid Panel Control

Indications for Use *(Describe)*
The Afinion™ Lipid Panel is an in vitro diagnostic test for quantitative determination of total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig) in serum. Values for low-density lipoprotein (LDL) cholesterol, non-HDL cholesterol and Chol/HDL ratio are calculated by the Afinion™ AS100 Analyzer. Chol, HDL cholesterol, Trig, and calculated LDL cholesterol, non-HDL cholesterol and Chol/HDL ratio are used in the diagnosis and treatment of disorders involving excess cholesterol in the blood and lipid and lipoprotein metabolism disorders.

Afinion™ Lipid Panel Control has been designed for use with the Afinion™ AS100 Analyzer and Afinion™ Lipid Panel. Afinion™ Lipid Panel Control is intended for use as assayed control material for total cholesterol (Chol), high-density lipoprotein (HDL) cholesterol and triglycerides (Trig). The controls should be used to confirm that the Afinion™ AS100 Analyzer System is working properly and provides reliable results.

For use in clinical laboratories and point of care laboratory settings.

For prescription use only.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Ruth A. Chesler -S